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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
WESTERBERG, NISSA M	
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1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,702	MORELLI ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 10* is/are pending in the application.

4a) Of the above claim(s) *9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 8, 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/29/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I and the electrolyte of a mixed glycolate/citrate salt of dimethylethanolamine in the reply filed on May 22, 2009 is acknowledged.

The traversal of the restriction requirement is on the grounds that the amended claims require a pH well outside the presently claimed range recited in the amended claims. In light of the amendments to the claims, this argument is persuasive. Therefore, the restriction requirement between groups I and II is withdrawn.

The traversal of the species election requirement is on the grounds that the alternatives presented are of a similar nature exhibiting a common property or activity by having a common structure and/or because the alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains, i.e., electrolytes.

Reproduced below are the guidelines for species elections of chemical compounds in national stage applications:

> Where a single claim defines alternatives of a Markush group, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, is considered met when the alternatives are of a similar nature. When the Markush grouping is for alternatives of chemical compounds, the alternatives are regarded as being of a similar nature where the following criteria are fulfilled:
>
> (A) all alternatives have a common property or activity; AND
>
> (B)(1) a common structure is present, that is, a significant structural element is shared by all of the alternatives; OR
>
> (B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

> The phrase "significant structural element is shared by all of the alternatives" refers to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity.
>
> The phrase "recognized class of chemical compounds" means that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention, i.e. each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

Applicants have not demonstrated that one of criteria (B)(1) or B(2) are met. Vitamin C and generic ethanolamines as in formula (I) or particular salt form of dimethylethanolamine in claim 8 do not possess a common structure element. There is no indication that vitamin C salts and ethanolamines are part of the art recognized class of "electrolytes". Therefore the species election requirement for the electrolyte is maintained.

Specification

2. The disclosure is objected to because of the following informalities: examples 3 – 6 include the ingredient "Dimethyl MEA". It is unclear what this ingredient is as Applicants have not provided a complete name to accompany this abbreviation.

Appropriate correction is required.

Claim Objections

3. The claims are objected to because of the following informalities: all claims must be consecutively numbered and no numbers may be skipped. The originally filed claims and the amended set of claims filed May 22, 2009 do not contain a claim 7. The original claim numbering is used throughout the action below. Appropriate correction is required.

Claim Rejections - 35 USC § 112 2nd Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 – 6, 8 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. No units are given for the percentages of the various ingredients. The specification (¶ [0031] of the PGPub of the instant application) indicates that all percentages are w/w relative to the total weight of the composition unless otherwise indicated. It is respectfully suggested that units be amended into the claim to remove any confusion as to the units for the percentages.

The phrase "in particular" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

The phrase "suitable carrier" is also indefinite as what would render a carrier suitable or unsuitable for the composition (e.g., interaction with the other ingredient) is not defined.

6. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4, from which claim 5 depends, requires the presence of one or more electrolytes. Claim 5 requires the composition of claim 4 "further comprising" one or more electrolytes. The percentage ranges for the electrolyte in dependent claim 5 is narrower than in claim 4, but it is unclear how many and how much of the electrolyte(s) are required to present in the composition of claim 5 or if claim 5 does not require additional electrolytes but rather specifies a narrower range for the amount of electrolyte present.

7. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 requires that the electrolyte of claim 4, which is present in an amount ranging from 0.001% to 5%, is an ethanolamine of formula (I) and is present in an "effective amount". It is unclear if the entire range of electrolyte amounts in claim 4 are effective amounts or if only a subset of the range is "effective". Claim 6 fails to state the function which is to be achieved and more than one effect can be implied from the specification or the relevant art so the claim is indefinite. As an electrolyte, the ethanolamines can adjust the ionic strength of the solution but ethanolamines can also have anti-aging effects on the skin (¶ [0006] of the PGPub of the instant application).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1 – 6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chevalier et al. (US 2003/0007985) in view of Guerrero et al. (US 5,425,939).

Chevalier et al. discloses compositions with an anti-wrinkle effect in a physiologically acceptable aqueous medium (¶ [0001]). The pH of the composition preferably ranges from about 5 to about 8, and more preferably from about 6 to about 7 and the pH of the composition can be adjusted by adding acids such as citric acid (¶ [0041]). In example 2, an anti-ageing serum comprising 0.2% xanthan gum; 0.2% PVM/MA decadiene crosspolymer (STABILEZE®; a methyl vinyl ether/maleic anhydride copolymer, ¶ [0055]); water, which reads on a suitable carrier; and 0.2% triethanolamine, an electrolyte according to formula (I) of claim 6 is prepared.

Chevalier et al. does not teach sclerotium gum.

Guerrero et al. discloses that many thickeners are known in the art but not all thickening agents are equally effective for any particular type of formulation (col 1, ln 21 – 24). Difficulties can arise in aqueous systems that include water-soluble vitamins that function as electrolytes or systems with low pH (col 1, ln 25 – 33). Low viscosity compositions that are too watery run off the treated skin areas and thickeners give a feel of substantivity and a desirable rich and creamy feel to the compositions (col 1, ln 10 – 20). Problems can also arise in maintaining the viscosity over time as the product is stored (col 1, ln 29 – 31). The use of sclerotium gum in combination with a hydrophobically-modified (meth)acrylate polymer forms an effective thickening system for cosmetic compositions that is particularly useful for building viscosity in compositions containing electrolytes (col 1, ln 65 – col 2, ln 2) that is also effective a low pH (col 1, ln

41 – 43). The sclerotium gum is present in an amount ranging from 0.005% to 1% (col 1, ln 50). Advantageously, the compositions have a pH ranging from about 8.0 to about 1.0, optimally between about 5.5 and 5 (col 3, ln 32 – 36).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use sclerotium gum as a thickener in the anti-ageing compositions taught by Chevalier et al. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Guerrero et al. discloses that sclerotium gum is a thickener that is effective at acidic pH values and can maintain the desired thickness of the product over time.

The amount of a specific ingredient in a composition and the pH of that composition are clearly result effective parameters that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. The amount of thickener required will depend on the desired consistency of the product, the pH of the product depending on the intended use and pH required to stabilize any acid or base sensitive ingredients in the composition and the amount of electrolytes present in the composition, which Guerrero et al. discloses can adversely effect anionic polymeric thickening agents (col 1, ln 25 – 27). The pH

range disclosed by Chevalier et al. is also encompassed by the range of about 4.5 to about 8 recited by the instant claims.

12. Claims 1 – 6, 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chevalier et al. and Guerrero et al. as applied to claims 1 – 6 and 10 above, and further in view of Perricone (US 5,554,647) and Ozlen (US 5,441,740).

As discussed in greater detail above, Chevalier et al. and Guerrero et al. disclose cosmetic compositions with an anti-wrinkling, anti-aging effect which comprise a thickener such as sclerotium gum that is effective in thickening compositions having acidic pH and/or electrolytes; a methyl vinyl ether/maleic anhydride copolymer; ethanolamine and water as a suitable carrier. The compositions of Chevalier et al. may include active agents such as the α-hydroxy acids glycolic or lactic acid as keratolytic or prodesquamant agents (¶ [0056]).

Neither reference explicitly prepares a composition with a mixed glycolate/citrate salt of dimethylethanolamine.

Perricone discloses that dimethylaminoethanol (dimethylethanolamine) is a precursor of acetylcholine that can be applied topically to treat aging skin (col 4, ln 10 - 13). The efficacy of the composition can be further enhanced by the inclusion of reductive agents such as α-hydroxy acids like glycolic acid (col 6, ln 6 – 9).

Ozlen discloses a topical composition for the treatment and alleviation of various skin conditions such as wrinkles (col 1, ln 47 – 51) that comprises both glycolic and citric acids (col 1, ln 66 – col 2, ln 6).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate dimethylethanolamine, glycolic acid and citric acid into a cosmetic composition. A composition comprising dimethylethanolamine, citric acid and glycolic acid results in the formation of a mixed glycolate/citrate salt of the dimethylethanolamine. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because as each of these ingredients is taught as useful for the treatment of wrinkling, aging skin by the prior art. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) **MPEP 2144.06**.

While the anti-serum composition of Chevalier et al. uses ethanolamine, Perricone discloses that the closely related compound dimethylethanolamine is a precursor of acetylcholine that can be topically applied to the skin to treat aging. Both Perricone and Chevalier et al. discloses that α-hydroxy acids can be included as active agents in the composition. Ozlen discloses that a combination of glycolic acid and citric acid is an effective combination of α-hydroxy acids for the treatment of aging skin than a single α-hydroxy acid. These acidic ingredients can also be included to adjust the pH of the composition in addition to providing a therapeutic benefit when the final composition is applied to the skin.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW